

Full Text PA-97-025

RESEARCH ON MUSCULOSKELETAL FITNESS AND SPORTS MEDICINE

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National Institute of Arthritis and Musculoskeletal and Skin Diseases

National Institute of Child Health and Human Development

National Institute of Nursing Research

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the National Institute of Nursing Research (NINR) invite investigator-initiated research grant applications to study a broad range of basic and clinical topics related to musculoskeletal fitness, exercise physiology and sports medicine. The National Center for Medical Rehabilitation Research of the National Institute of Child Health and Human Development (NCMRR/NICHD) encourages applications for both basic and clinical studies of musculoskeletal fitness and exercise physiology of persons with physical disabilities.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement (PA), Research on Musculoskeletal Fitness and Sports Medicine, is related to the priority area of physical activity and fitness. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238). The PA is related to issues in the 1996 Surgeon General's Report on "Physical Activity and Health" (Stock No. 017-023-00196-5).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Foreign institutions are eligible to apply for regular research project grants (R01).

MECHANISM OF SUPPORT

Under this program announcement, the NIAMS and NICHD will support investigator-initiated research project grants (R01), First Independent Research Support and Transition (FIRST) (R29) awards, small grants (R03), program projects (P01), career development grants (K01, K02, K08), and Investigator-Initiated Interactive Research Project Grants (IRPG.) The IRPG is described in PA-96-001, published in the NIH GUIDE, Vol. 24, No. 35, October 6, 1995. The Principal Investigator and participating investigators will plan, direct, and perform the research. Applicants for program project grants are requested to contact the NIAMS representative listed below as early as possible in the planning stages. The NINR will support individual research project grants (R01 and R29.)

RESEARCH OBJECTIVES

Background

Physical activity builds strong muscles and bones and improves flexibility and balance at all stages of life. Musculoskeletal fitness and physical activity protects individuals against over-exertion or strains, preventing consequences including low back pain, muscle tears, bone fractures, tendon ruptures, and other disorders.

Musculoskeletal fitness delays the onset of frailty as people age and protects against disorders like osteoporosis. Additionally, fitness lowers risk for obesity, cardiovascular disease, and other chronic illnesses. There is not a strong scientific research basis for understanding how the body integrates molecular mechanisms to coordinate fitness in muscle, bone, tendon, and ligament.

Recent surveys included in the Surgeon General's Report on Physical Fitness show that approximately one-fourth of U.S. adults are physically inactive. It is important to promote exercise for inactive people that improves fitness yet does not seem onerous.

While we know much of the vigorous regimens used by body-builders and long distance runners, we have little experimental evidence of how shorter, more focussed patterns of exercise can effectively build muscle and bone strength. We have even less information about the physiological bases for appropriate musculoskeletal rehabilitation interventions and the exercise needs of persons with physical disabilities.

There is a health problem also for those who engage in extremely strenuous exercise or sports regimens. More than 30 million young Americans participate in organized competitive sports, and one of every two adult Americans exercises regularly. This has led to an increase in activity-related injuries, which is substantial, extending beyond sports into its impact on the workforce. It has been estimated that 17 million persons in this country sustain significant injury from sports or recreational participation yearly. One-third of the 15 million joggers will sustain an injury that involves the musculoskeletal system. During 1995 football injuries resulted in 390,000 emergency room visits, while skiing resulted in 330,000 visits. Evidently understanding the causes, prevention, and treatment of athletic and recreational injury is a major health issue.

Many currently recommended sports and exercise practices are not based on strong scientific evidence. The empirical designs of many protective devices are not founded in fundamental biomechanical studies. Additionally, there is a strong scientific understanding of the normal physiology of muscle, but not a large base of research into muscle metabolism, hypertrophy and injury during exercise, strength training, and disuse. Feedback mechanisms by which the muscle senses and communicates its mechanical requirements are unknown. Similarly, bone strength increases following muscle strength, but the molecular couplers of the two actions have not been characterized.

Research efforts have yielded many improvements in training athletes, preventing injuries and treating patients. Technological advances have improved the practice of sports medicine. Further improvements in the use of new technologies and information systems are likely to improve methods of preventing, diagnosing, and treating sports injuries. Surveillance and treatment can

be improved with the development of standard and normative measures of musculoskeletal fitness.

Improved knowledge can be gained through increased basic science research related to sports medicine and in applying the information gained to practical problems in this field. NIAMS promotes increased basic science research related to exercise and sports medicine to gain improved knowledge about normative measures of musculoskeletal fitness. An aim is to develop appropriate exercise patterns to build muscle and bone strength for men and women who are relatively inactive as well as world class athletes. Exercise patterns should be appropriate throughout the life spectrum, and not limited by performance level or the presence of physical or psychological challenges.

Objectives and Scope

This solicitation is intended to stimulate research that provides an expanded foundation of basic science knowledge related to musculoskeletal fitness and sports medicine. Additionally, it is intended to encourage use of the best available scientific information in important clinical and applied aspects related to exercise, training, prevention, treatment and rehabilitation.

This program announcement includes a wide range of basic and applied research on various aspects of musculoskeletal fitness. Applicants are encouraged to submit high scientific quality research projects in any area related to the broad objectives of this program announcement. No order or priority of areas of interest has been established.

General Considerations - A large research effort is required to establish a firm scientific foundation for a basic and applied program in musculoskeletal fitness and sports medicine. Several aspects of musculoskeletal fitness and injury require increased knowledge: athletic performance during competition; training and prevention; treatment, and rehabilitation. Research in these areas may involve various types of individuals, such as young children, adolescents, mature adults, aged, professional athletes, men or women. Because the appropriate fitness information may be different for each type of individual as they experience different possible phases of musculoskeletal fitness or injury, research should be carefully directed to the results applied to a particular combination. This includes differences between endurance and resistance exercise regimens.

Examples of investigations of interest to the NIAMS include but are not limited to research on:

1. Muscle Physiology and Metabolism - Studies on changes in metabolic, structural and contractile proteins following patterns of disuse, and endurance and resistance strength training. Explore the interrelationships and molecular steps between mechanical stimuli and biochemical changes. Determine how molecular responses differ depending on demands of endurance and resistance training. Relate altered use of chemical fuel to training status of muscle, performance responses, and health prevention. Investigate changes in fiber recruitment patterns and motor unit control. Develop a mechanistic understanding of the growth and maturation of muscle as related to use and specialization.

2. Muscle membranes - Studies on changes on both external and internal muscle membranes (e.g. sarcoplasmic reticulum) in response to patterns of use. This includes studies on receptors for circulating factors (hormones), complexes involved in excitation-contraction coupling, and surfaces involved in the transfer of force, such as the extracellular matrix and the myotendinous junction.

3. Exercise Pathophysiology - Investigations of the damage and healing of tissue from factors such as mechanical or thermal overloading or systemic biochemical changes. Study molecular bases of fatigue in contractile, metabolic, and excitation-contraction systems. Explore the role of heat shock proteins in protecting tissue during bouts of mild or extreme hyperthermia.

4. Injury Mechanisms - Determine the mechanical forces and biochemical environments that weaken and injure muscle, bone, and connective tissues. Establish the forces and force distributions within joint structures and tissues, both during normal function and during trauma. Explore influence of age and gender on structural aspects that might influence location and severity of specific types of injury. Establish the conditions present during competitive sports and recreational activities that may lead to damaged tissue. Compare overuse versus traumatic injuries. Investigate the role of neuromuscular control and fatigue in injuries.

5. Role of Exercise in the Prevention and Treatment of Bone and Joint Diseases - Explore the interrelationships and molecular steps between mechanical stimuli and biochemical changes. Determine how molecular responses differ depending on demands of endurance and resistance training. Determine relationship between exercise patterns and degenerative joint diseases, such as osteoarthritis. Establish possible mechanisms for prevention of bone diseases including osteoporosis.

6. Healing - Improved general understanding of the natural healing process for muscle, bones, and connective tissue. Determine what interventions are most successful in enhancing healing

and under what conditions should these therapies be applied. Establish the role of cytokines in inflammation and healing. Investigate healing from localized tissue damage as a preliminary step in strengthening and/or enlarging muscle and other connective tissue.

7. Circulation - Improved understanding of changes in circulation within the musculoskeletal system in response to patterns of use. This announcement encourages studies on the mechanisms involved in altered microvasculature and extra-vascular circulation in muscle, bone, and joints. Investigators should explore differences due to endurance and resistance training.

8. Fitness and Wellness - Determine how molecular responses differ depending on demands of endurance and resistance training. Provide improved understanding of how musculoskeletal activity leads to general body fitness. This would include homeostasis of the immune, endocrine, and neuroendocrine systems. Explore how exercise patterns affect different components of the immune system, determining molecular mediators.

9. Fitness and Nutrition - Explore how regular exercise affects body need and use of nutrients. Study how patterns of musculoskeletal activity differentially alter body allocation of metabolites and energy supplies, exploring intercellular and inter tissue communications. Study the role of nutrition and dietary supplements in improving performance and reducing fatigue.

10. Clinical Studies - Provide improved repair and replacement of injured muscle, connective tissues and joints. Characterize improvements in materials and methods for transplantation, augmentation, and replacement of ligaments and tendons. Common sports injuries and symptoms include ligaments of the knee (such as anterior cruciate ligaments and medial collateral ligaments), patellar pain, and rotator cuff syndrome. Study surgical and non-surgical treatments, including rehabilitation modalities.

11. Junctional Assessment and Gait Analysis - Establish simple, quantitative measures of joint motion and forces that may be uniformly applied at most research and clinical sites. Document the use of such evaluations for improved pre-injury screening and post-injury surveillance.

12. Epidemiology - Define the incidence and natural history of injury in competitive sports and recreational activities. Establish risk factors for incurring injuries and for the progression of an injury to a more serious medical problem. Determine relationships between sequential chronic and acute injuries.

13. Prevention and Training - Develop improved protective sporting equipment and training methods, especially for high risk competitive and recreational activities. Determine the short and long range benefits and side-effects from using anabolic steroids and other chemical enhancers of performance. Establish more completely the interrelations between neuromuscular and connective tissue response to training.

Applications of interest to the NCMRR/NICHD should be related to issues of musculoskeletal fitness, exercise physiology, and sports medicine relevant to people with physical disabilities. Especially encouraged are basic and clinical studies that will lead to the development of rehabilitation interventions to enhance physical fitness, prevent further disability through overuse injuries, and lead to greater independence and physical functioning.

NINR is interested in related research on musculoskeletal fitness and physical activity across the age continuum, especially studies on: exercise and primary prevention, body fitness and wellness, and clinical studies that test interventions that influence patient health outcomes and reduce costs and demand for care.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their sub- populations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Submit applications on the grant application form PHS 398 (rev. 5/95); applications will be accepted at the standard receipt deadlines shown. Application kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714; email: ASKNIH@odrockm1.od.nih.gov. The number (PA-97-025) and title (RESEARCH ON MUSCULOSKELETAL FITNESS AND SPORTS MEDICINE) must be typed in Section 2 on the face page of the application.

The completed original application and five legible copies must be sent or delivered to:

DIVISION OF RESEARCH GRANTS
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817-7710 (for express/courier service)

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications that are complete will be reviewed in accordance with the usual NIH peer review procedures for research grants (Study Section). Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council.

Review Criteria for Research Grants

- o Scientific, technical, or medical significance and originality of the proposed research;
- o Appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research;
- o Qualifications and research experience of the Principal Investigator and staff, particularly, but not exclusively, in the area of the proposed research;
- o Availability of the resources necessary to perform the research;
- o Appropriateness of the proposed budget and duration in relation to the proposed research;

- o Adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

The initial review group will also examine the provisions for the protection of human and animal subjects, and the safety of the research environment.

Review Criteria for Career Awards

Candidate

- o Quality of the candidate's academic and clinical record,
- o Potential to develop as an independent researcher;
- o Commitment to a research career; and
- o Likelihood that the plan will contribute substantially to the achievement of scientific independence.

Career Development Plan

- o Likelihood that the career development plan will contribute substantially to the scientific development of the candidate;
- o Appropriateness of the content, the phasing, and the proposed duration of the career development plan for achieving scientific independence;
- o Consistency of the career development plan with the candidate's career goals; and
- o Quality of the proposed training in responsible conduct of research.

Research Plan

Reviewers recognize that an individual with limited research experience is less likely to be able to prepare a research plan with the breadth and depth of that submitted by a more experienced

investigator. Although it is understood that K08 applications do not require the level of detail necessary in regular research grant proposals, a fundamentally sound research plan must be provided. In general, less detail is expected with regard to research planned for the later years of the award, but the application should outline the general goals for these years.

- o Appropriateness of the research plan to the stage of research development and as a vehicle for developing the research skills as described in the career development plan;
- o Scientific and technical merit of the research question, design and methodology;
- o Relevance of the proposed research to the candidate's career objectives; and
- o Adequacy of the plan's attention to gender and minority issues.

Mentor

- o Appropriateness of mentor's research qualifications in the area of this application;
- o Quality and extent of mentor's proposed role in providing guidance and advice to the candidate;
- o Previous experience in fostering the development of researchers; and
- o History of research productivity and support.

Environment and Institutional Commitment

- o Applicant institution's commitment to the scientific development of the candidate and assurances that the institution intends the candidate to be an integral part of its research program;
- o Adequacy of research facilities and training opportunities;
- o Quality and relevance of the environment for scientific and professional development of the candidate; and

o Applicant institution's commitment to an appropriate balance of research and clinical responsibilities.

AWARD CRITERIA

Applications recommended by a National Advisory Council will be considered for funding on the basis of overall scientific and technical merit, program needs and balance, and availability of funds.

INQUIRIES

For further information about programs in the National Institute of Arthritis and Musculoskeletal and Skin Diseases, investigators are encouraged to contact:

Richard W. Lymn, Ph.D.

Muscle Biology and Musculoskeletal Fitness Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Natcher Building Room 5AS 49E

Bethesda, Maryland 20892-6500

Telephone: (301) 594-5128

FAX: (301) 480-4543

e-mail: lymnr@ep.niams.nih.gov

Investigators concerned with orthopedic studies are encouraged to contact:

James S. Panagis, M.D.

Orthopedics Program Director

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Natcher Building Room 5AS 37K

Bethesda, Maryland 20892-6500

Telephone: (301) 594-5055

FAX: (301) 480-4543

e-mail: panagisj@ep.niams.nih.gov

For information about support by the National Center for Rehabilitation Research, contact:

Danuta Krotoski, Ph.D.

National Center for Medical Rehabilitation Research
National Institute of Child Health and Human Development
Building 61E, Room 2A-03
Bethesda, MD 20893-7510
Telephone: (301) 402-2242
Email: krotoskd@hd01.nichd.nih.gov

For information concerning research interests of the National Institute of Nursing Research,
contact:

J. Taylor Harden, PhD, RN
Division of Extramural Programs
National Institute of Nursing Research
Building 45, Room 3AN-12
45 Center Drive, MSC 6300
Bethesda, MD 20892-6300
Telephone: (301) 594-5976
FAX: (301) 480-8260
Email: THARDEN@ep.ninr.nih.gov

Direct inquiries regarding fiscal matters to:

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FAX: (301) 480-8256
Email: JCAROW@ep.ninr.nih.gov

AUTHORITY AND REGULATIONS

These programs are described in the Catalog of Federal Domestic Assistance No. 93.846, (Arthritis, Musculoskeletal and Skin Diseases Research), No. 93.929 (Medical Rehabilitation Research,) and No. 93.361 (Nursing Research). Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 410, 78th Congress, as amended, 42 USC 241) and administered under PHS grants policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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[Return to PA Index](#)

[Return to NIH Guide Main Index](#)